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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/694,235	10/27/2003	N. Sandor Racz	2102-4389US	3743
24247	7590	12/23/2010		
TRASKBRITT, P.C. P.O. BOX 2550 SALT LAKE CITY, UT 84110			EXAMINER CAMPBELL, VICTORIA P	
			ART UNIT	PAPER NUMBER
			3763	
			NOTIFICATION DATE	DELIVERY MODE
			12/23/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

USPTOMail@traskbritt.com

Office Action Summary	Application No. 10/694,235	Applicant(s) RACZ ET AL.	
	Examiner VICTORIA P. CAMPBELL	Art Unit 3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 November 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-9,12-23,25-32,34 and 35 is/are pending in the application.
- 4a) Of the above claim(s) 7,13,19,22 and 26 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3-6,8,9,12,14-21,23,25,27-32,34 and 35 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 11/4/10 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>11/4/10</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This is the first Office Action following the second Request for Continued Examination based on the 10/694235 application filed October 27, 2003. Claims 1, 3-6, 8, 9, 12, 14-18, 20, 21, 23, 25, 27-32, 34, and 35 as amended and newly presented in the response filed November 4, 2010 are currently pending and considered below.

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on November 4, 2010 has been entered.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claim 34 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claim is dependent on a currently cancelled claim and has therefore not been further treated on the merits.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Art Unit: 3763

7. Claims 1, 3-6, 8, 9, 12, 14-18, 20, 21, 23, 25, 27-32, and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent 5,871,470 to McWha in view of USPN 5,250,035 to Smith et al.

Regarding claims 1-6, 8, 9, 12, 14, 15, 29, and 32, McWha teaches a flexible spinal needle catheter assembly (10) comprising: a flexible needle catheter (12), said flexible needle catheter defining a hollow bore (14) for conveying medicating agent therethrough, said bore extending through a length of said flexible needle catheter, said flexible needle catheter having a proximal end which defines a leading edge (16; Fig. 2); a support needle releasably secured to said flexible needle catheter (22), said support needle being disposed within said hollow bore of said flexible needle catheter (Fig. 2), said support needle having a first end which defines a pencil point, non-cutting piercing point (27) configured for penetrating the dura mater of a patient (46; Fig. 6), said support needle having an outside diameter sized so that upon withdrawal of the flexible spinal needle catheter assembly from a dura mater of a spine of a patient, subsequent to an insertion of said assembly through the dura mater, a puncture opening produced by said insertion is of dimensions which permit the dura mater substantially to reseal said puncture opening formerly occupied by the flexible spinal needle assembly within said dura mater (The examiner notes that the phrase beginning with "sized so that" has been interpreted as functional language and as such, the prior art need be only capable of performing the function above, and based on the size chosen, McWha would have been capable of performing the above function.), said support needle defining a hollow lumen (24) which extends along a length of said support needle and an opening (29),

Art Unit: 3763

defined proximate said first end, which communicates the environment with said lumen, said support needle being dimensioned such that said first end of said support needle is positioned outside of said bore the opening being positioned contiguous to the leading edge of the flexible needle catheter after being inserted into the patient's body (the examiner notes that the flexible needle catheter is not extended from the position shown in Figure 2 to that shown in Figure 3 until after insertion in the body, and as such, as the opening passes the leading edge, they are contiguous after insertion into the patient's body), said non-cutting piercing point and said opening being positioned outside of said bore (Fig. 3), and a solid stylet (25), releasably secured within said lumen, said stylet being positioned in a first condition to preclude access from the environment to said lumen through said opening (Col. 5, lines 61-65). Furthermore, McWha teaches that said leading edge of said flexible needle catheter is positioned proximate said pencil point tip (Fig. 3), that the flexible needle assembly has a leading edge configured and arranged to provide a feedback signal to indicate dural puncture (Col. 2, lines 1-8), that a rear end of said support needle carries a support hub (30) having a first attach structure (33); and a proximal end of said flexible needle carries a flexible needle hub (20) having a second attach structure (32) configured to removably attach to the first attach structure carried by said support hub (by rotation), that the first and second attach structures comprise a luer lock type connection (17; Fig. 2), and that the flexible needle hub is configured for substantially unobtrusive attachment to a patient's skin by way of an intermediary adhesive element (the examiner notes that the device of McWha is capable of being taped to a patient's skin). Additionally, McWha teaches that a rear

Art Unit: 3763

end of said support needle carries a support hub (30); and a proximal end of said flexible needle carries a flexible needle hub (20) having a detach structure (32) configured to detach the flexible needle hub from the support hub (by rotation), that a proximal end of said flexible needle carries a flexible needle hub (20); and a rear end of said support needle carries a support hub (30) having a detach structure (33) configured to detach the flexible needle hub from the support hub, that said flexible needle comprises a force absorbing structure to prevent kinking when the flexible needle is overly flexed (outer hub sleeve, see Figure below), and that said force absorbing structure comprises a flexible kink sleeve disposed on a portion thereof (see Figure below). McWha further teaches that said stylet is slidably mounted in said support needle (Fig. 1), that said first end of said flexible needle catheter is tapered into a curve to blend smoothly into the outer surface of said support needle (Fig. 4A), and that said flexible needle catheter is disposed on an outer surface of said support needle (Fig. 2).

However, McWha does not teach that the flexible needle catheter is comprised of a plastic. Smith et al teach a spinal needle catheter for administration of anesthetics and/or analgesics formed of a plastic (Abstract, Col. 1, lines 36-41). At the time of invention, it would have been obvious to one having ordinary skill in the art to form the flexible needle catheter of McWha using the plastic (for example, Teflon) of Smith et al to take advantage of the more lubricious properties thereof (Col. 3, lines 19-33).

Regarding claims 16-18, 20, 21, 23, and 35, McWha teaches a flexible spinal needle assembly (10) for inserting a distal end of a flexible spinal needle through dura mater into a spine of a patient, said flexible spinal needle assembly comprising: a

Art Unit: 3763

flexible needle (12); a support needle (22) having a proximal end (20) and a pencil point non-cutting piercing point at a distal end (27), said support needle being releaseably secured to said flexible needle to resist relative motion between a distal end of said flexible needle and said pencil point non-cutting piercing point during insertion of said flexible spinal needle assembly into a patient (via threads 32, 33); wherein said flexible needle is carried exterior to said support needle to expose said non-cutting piercing point when said assembly is positioned for said inserting (Fig. 3). McWha further teaches that said flexible needle has an exterior diameter configured such that withdrawal of said flexible needle from said dura mater, subsequent to insertion of the flexible needle assembly therethrough, permits said dura mater substantially to reseal a space formerly occupied by said flexible needle, and a tip and a flexible needle body of said flexible needle are of substantial elongated extent to be further extendable into the dura mater upon extraction of said support needle (The examiner notes that the phrase beginning with “configured such that” has been interpreted as functional language and as such, the prior art need be only capable of performing the function above, and based on the size chosen, McWha would have been capable of performing the above function.), and that said proximal end of said support needle carries a support hub (30) having a first attach structure (33); a proximal end of said flexible needle carries a flexible needle hub (20) having a second attach structure (32) configured to interface in removable interference with said first attach structure carried by said support hub (via rotation). Furthermore, McWha teaches a distal end of said assembly being constructed to provide a perceptible feedback signal when said distal end of said

Art Unit: 3763

flexible needle penetrates said dura mater (Col. 2, lines 1-8), that the flexible needle hub further being configured for attachment to medical fluid transfer equipment having structure to form a luer lock type connection (17), and that said flexible needle comprises a kink sleeve disposed on a portion thereof, said kink sleeve configured to prevent kinking of said flexible needle when said flexible needle is extended beyond the substantial flexure point during use (outer hub sleeve; see Figure below).

However, McWha does not teach that the flexible needle catheter is comprised of a plastic. Smith et al teach a spinal needle catheter for administration of anesthetics and/or analgesics formed of a plastic (Abstract, Col. 1, lines 36-41). At the time of invention, it would have been obvious to one having ordinary skill in the art to form the flexible needle catheter of McWha using the plastic (for example, Teflon) of Smith et al to take advantage of the more lubricious properties thereof (Col. 3, lines 19-33).

Regarding claim 25, McWha teaches a flexible spinal needle (10) comprising: a support needle (22) having a pencil point, non-cutting piercing tip (27), said support needle defining an interior lumen and an opening (the lumen begins at opening 29), said opening communicating said interior lumen with the exterior of said support needle; a flexible needle body (12) comprising an elongated hollow tube, said flexible needle body configured to be slidably mounted on an exterior of said support needle (Figs. 2 and 3); and a flexible kink sleeve (the examiner notes that all structures have some degree of flexibility and as such has considered the kink sleeve of McWha to be flexible) disposed on a portion of said flexible needle body, said flexible kink sleeve being configured to prevent kinking of said flexible needle body, when said flexible needle body is bent

Art Unit: 3763

beyond a flexible structural resilience thereof during use (outer hub sleeve; see Figure below).

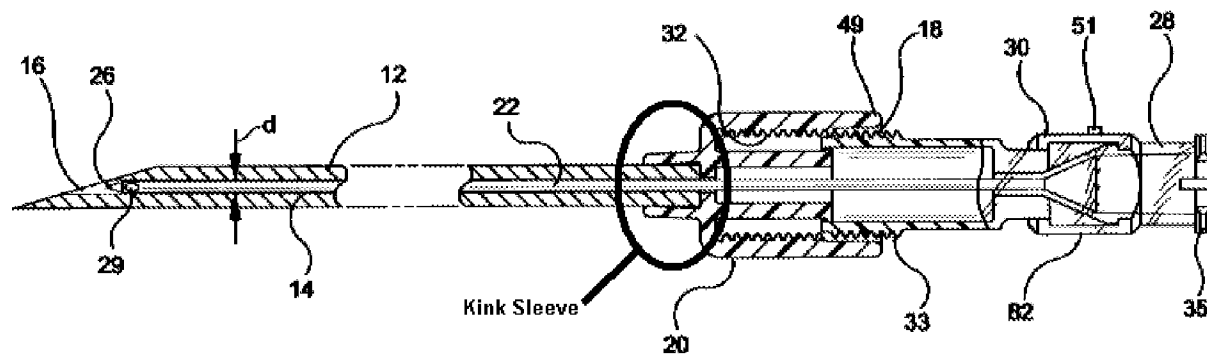
However, McWha does not teach that the flexible needle catheter is comprised of a plastic. Smith et al teach a spinal needle catheter for administration of anesthetics and/or analgesics formed of a plastic (Abstract, Col. 1, lines 36-41). At the time of invention, it would have been obvious to one having ordinary skill in the art to form the flexible needle catheter of McWha using the plastic (for example, Teflon) of Smith et al to take advantage of the more lubricious properties thereof (Col. 3, lines 19-33).

Regarding claim 27, McWha teaches a flexible spinal needle assembly (10) comprising: a support needle (22) comprising a first end defining a pencil point, non-cutting piercing point (27), and a hollow bore (24) with an opening (29) proximate said first end allowing access to said bore; and a flexible needle (12) slidably mounted on an exterior portion of said support needle (Figs. 2 and 3) such that said first end of said support needle protrudes from said flexible needle exposing said pencil point, non-cutting piercing point and said opening, wherein said flexible needle has sufficient transverse flexibility to accommodate patient torso bending movement so as to substantially reduce a patient's awareness of the presence of the flexible needle (Fig. 3).

However, McWha does not teach that the flexible needle catheter is comprised of a plastic. Smith et al teach a spinal needle catheter for administration of anesthetics and/or analgesics formed of a plastic (Abstract, Col. 1, lines 36-41). At the time of invention, it would have been obvious to one having ordinary skill in the art to form the

Art Unit: 3763

flexible needle catheter of McWha using the plastic (for example, Teflon, a medical grade plastic) of Smith et al to take advantage of the more lubricious properties thereof (Col. 3, lines 19-33).



12. Claims 30 and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over McWha and Smith et al in view of USPGPub 2005/0070881 A1 to Gribbons et al.

McWha and Smith et al teach the limitations of claim 1 as taught above, but fail to teach or disclose a flat ribbon internal spring or metal band in the first end of the flexible needle catheter. Gribbons et al teach a flat metal ribbon or band (140) within the body of a catheter in order to provide support. It would have been obvious to one having ordinary skill in the art at the time the invention was made to add the flat metal band of Gribbons et al to the tip of the flexible needle catheter of McWha and Smith et al in order to further stabilize the tip to prevent bending during the insertion process.

Response to Arguments

8. Applicant's arguments with respect to the above claims have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

9. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. See PTO-892.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to VICTORIA P. CAMPBELL whose telephone number is (571)270-5035. The examiner can normally be reached on Monday-Friday, 7-3.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3763

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Victoria P Campbell
Examiner, AU 3763

/Nicholas D Lucchesi/
Supervisory Patent Examiner, Art Unit 3763